K102467

510(k) Summary of Safety and Effectiveness

APR - 7 2011

August 23, 2010

Submitted by: Joe Wiener
Managing Partner
Address: UTA
3318 Successful Way
Dayton, Ohio 45414
Telephone: 937 608 0557

Classification Name: Endosseous Dental Implant Abutment 21 CFR 872.3630

Trade Name: UTA and UHA

Legally Marketed Device: Implant Innovations Preformance Abutment Posts and Temporary Cylinders K061969 (now under Biomet 3i)

Device Description: UHA is a healing abutment which is a PEEK screw-retained post. UTA is a screw-retained temporary abutment which is a PEEK post with a predefined apex so a preformed tooth can be attached. Screws are available for Astra Tech 3.5/4.0 &4.5/5.0, Biohorizon 3.2/4.5/6.0, Biomet 3.4/4.0/5.0, Nobel Biocare Branemark, Nobel Biocare Active Internal 4.1/5.0(RP/WP) & 3.5(NP), Nobel Biocare Select 4.3/5.0(RP/WP) & 3.5(NP), Nobel Biocare Replace 4.3, Straumann Bone Level 4.0 NC &RC, Zimmer 3.75/4.5/6.0.

Indications for Use: The UTA is intended for use to fabricate and support provisional restorations that aid in creating proper emergence profiles and support gingival architecture throughout the healing phase. It is for use in single tooth restorations in the maxilla or mandible, with non occlussal loading. The UTA can be used for up to one hundred eighty days (180) intra orally.

The UTA is compatible with AstraTech 3.5/4.0 & 4.5/5.0, Biohorizons 3.2/4.5/6, Biomet 3.4, 4.1 & 5, Nobel Biocare Branemark, Nobel Biocare Active Internal RP(4.1/5)&NP(3.5), Nobel Biocare Select NP(3.5)& RP/WP(4.3/5), Nobel Biocare Replace 4.3, Straumann Bone Level NC &RC (4), and Zimmer 3.75, 4.5 &6.

UHA are placed on top of implants to protect the inner components of the implants throughout the healing phase. UHA creates support for gingival architecture and can be used with cement-retained temporary prostheses. It should be placed in non occlusal loading. It can be used for up to 180 days.

The UHA is compatible with AstraTech 3.5/4.0 & 4.5/5.0, Biohorizons 3.2/4.5/6, Biomet 3.4, 4.1 & 5, Nobel Biocare Branemark, Nobel Biocare Active Internal RP(4.1/5)&NP(3.5), Nobel Biocare Select NP(3.5)& RP/WP(4.3/5), Nobel Biocare Replace 4.3, Straumann Bone Level NC &RC (4), and Zimmer 3.75, 4.5 &6.

Testing:
Fatigue and static testing comparing the UTA to predicate temporary abutments was conducted. The ISO 14801 test method was modified for 1 million cycles (adjusted for the less than 180 day use of temporaries) and the setup did not include the 3mm holding line because the temporary abutments are too short to allow this type of fixation.

Substantial Equivalence:
The UTA and UHA are of similar material to the predicate abutments, PEEK. The indications for UTA and UHA are a subset of the predicate indications (e.g. UTA is only for single tooth restoration and neither UTA nor UHA would normally be used in completely edentulous cases). UTA and UHA are for use for the same time period, up to 180 days, as the predicate device from Biomet 3i.

Static testing showed similar strength for the UTA and the implant company's temporary abutments for Astra Tech, Biomet, and Zimmer. Fatigue testing was completed for UTA used with Astra Tech in both screw sizes, with Biomet 3i in both sizes, Nobel Select 3.5 and Nobel Biocare Branemark. The results were similar to fatigue testing of AstraTech 3.5/4 with its PEEK temporary abutment and Biomet 3.4 with its PEEK temporary abutment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

UTA
C/O Ms. Angela Blackwell
Senior Consultant
Biologics Consulting Group
3318 Successful Way
Dayton, Ohio 45414

APR - 7 2011

Re: K102467
Trade/Device Name: UTA and UHA
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: March 30, 2011
Received: March 31, 2011

Dear Ms. Blackwell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _K102467_____

Device Name: __UTA and UHA_____

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
510(k) Number K102467